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REMARKS

Upon entering the above amendment claims 1-2, 11, 13 and 19-20 are pending in the present application. Applicants have amended claim 1 by inserting the subject matter of claim 3. Applicants have made claim 11 dependent of claim 1. Applicants have canceled claims; however, Applicants reserve the right to file Divisional Applications concerning non-elected subject matter and Continuation Application for all other subject matter. Claim 1 is an independent claim. Applicants have not raised any issue of new matter.

Applicants wish to thank the Examiner for the Interview of November 15, 2004. Applicants' representative feels that much was gained by the meeting. Applicants believe the previous amendments are consistent with the discussion of November 15, 2004.

Issue Under 35 U.S.C. §112, Second Paragraph

Claims 1-3, 11, 13, 1, 16, 16, 18-20, 23 and 24 stand rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite. The Examiner has identified the terms immunoreactive, antigenic determinants and molecular weight as being used in an indefinite manner.

Applicants have amended the claims in a manner to address the Examiner's concerns. Applicants respectfully request

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withdrawal of the 35 U.S.C. §112, second paragraph rejection.

Issue Under 35 U.S.C. §112, First Paragraph

Claims 3, 18, 23 and 24 stand rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly fails to provide an enabling disclosure for any fragment of the isolated protein. The Examiner has maintained the same rejection. Applicants traverse this assertion.

As stated in the Interview of November 15, 2004, Applicants assert that the specification clearly enables an isolated 37kd protein from *Eimeria acervulina* consisting of the amino acid sequence set forth in SEQ ID NO.:2 and a vaccine containing the 37kd protein.

Applicants have disclosed the information that a skilled artisan would need to understand how to locate, isolate or synthesize and use immunogenic determinant by indicating this is done by Kyte-Doolittle plots, by Hopp-Woods plots and by surface-exposure plots of the *Eimeria* LDH. Proof of the effectivity of using such tools was provided pointing to the paper by Margalit et al (1987, J. of Immunol., vol. 138, p.2213-2229).

Applicants respectfully submitted the publication by Schaap et al. (2004, Parasitology, vol. 128, p. 603-616). This journal article was published after the priority date of the application. Schaap et al. describes the cloning and the sequences of LDH's

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from the Eimeria species acervulina, tenella and maxima.

Applicants respectfully assert that the previously presented claims were enabled and would not lead to an undue burden of experimentation. However, to expedite prosecution, Applicants have amended the claims as agreed during the November 15, 2004 Interview. Therefore, Applicants respectfully request withdrawal of the 35 U.S. §112, first paragraph rejection.

Issue Under 35 U.S.C. §102(b)

Claims 1-3, 11, 13, 16-20, 23-24 and 26 stand rejected under 35 U.S.C. §102(b) as being anticipated by Shirley (Parasitology, 71:369-376, 1975). Applicants assert that patentable distinction exists between the cited prior art and the present invention.

Distinction Between the Present Invention and Shirley

As presented in a previous response, Shirley allegedly discloses lactate dehydrogenase enzyme from E. acervulina. Shirley discloses a biochemical characterization of crude samples from Eimeria sporozoites, merozoites and oocysts. The characterization applied is starch-gel electrophoresis and substrate incubation.

The Examiner maintains an inherency argument that the isolated protein of the present invention is present within the mixture disclosed. Furthermore, the Examiner maintains that the

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vaccine claim is an intended use of the enzyme.

Shirley fails to disclose or suggest a protein expressed *in vitro*, comprising an isolated protein found intracellularly in *Eimeria* and is represented by the amino acid sequence shown in SEQ ID NO:2 and a vaccine for the protection of poultry against Coccidiosis comprising an effective amount of an isolated protein as described above.

Shirley, at best, discloses a native intact *Eimeria* LDH protein. Shirley never mentions using these proteins as vaccines.

A vaccine claims can be clearly patentable, it is novel, even if the protein itself is anticipated. Shirley fails to discuss a vaccine; thus, Shirley fails to anticipate a "vaccine" claim.

Shirley fails to disclose each element of the present invention as set forth in the claims.

Applicants respectfully request withdrawal of the 35 U.S.C. §102(b).

Issue Under 35 U.S.C. §102(b)

Claims 1-3, 16-18 and 23 stand rejected under 35 U.S.C. §102(b) as being anticipated by Kuccera (Folia Parasitologica 36(4):295-299). Applicants assert that patentable distinction exists between the cited prior art and the present invention.

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Distinction Between the Present Invention and Kucera

As presented in an earlier response, Kucera allegedly discloses lactate dehydrogenase enzyme from *E. acervulina*. Kucera discloses methods for performing techniques of Shirley (see above) with a certain type of electrophoresis equipment. Homogenized *Eimeria* oocysts are used.

The Examiner maintains an inherency argument that the isolated protein of the present invention is present within the mixture disclosed. Furthermore, the Examiner maintains that the vaccine claim is an intended use of the enzyme.

Kucera fails to disclose or suggest a protein expressed *in vitro*, comprising an isolated protein found intracellularly in *Eimeria* and is represented by the amino acid sequence shown in SEQ ID NO:2 and a vaccine for the protection of poultry against Coccidiosis comprising an effective amount of an isolated protein as described above.

Kucera, at best, discloses a native intact *Eimeria* LDH protein. Kucera never mentions using these proteins as vaccines.

Again, Applicants respectfully assert that Kucera cannot anticipate a "vaccine" claim.

Kucera fails to disclose each element of the present invention as set forth in the claims.

Applicants respectfully request withdrawal of the 35 U.S.C. §102(b).

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Issue Under 35 U.S.C. §102(b)

Claims 1-3, 16-18 and 23 stand rejected under 35 U.S.C. §102(b) as being anticipated by Nakamura et al (Journal of Veterinary Medical Science, 53(6):1101-1103, 1991. Applicants assert that patentable distinction exists between the cited prior art and the present invention.

Distinction Between the Present Invention and Nakamura et al.

As previously presented, Nakamura et al. allegedly discloses lactate dehydrogenase enzyme from *E. acervulina*. Nakamura et al. discloses *Eimeria* enzyme starch-gel electrophoresis, and uses enzymes samples from sporulated oocysts.

The Examiner maintains an inherency argument that the isolated protein of the present invention is present within the mixture disclosed. Furthermore, the Examiner maintains that the vaccine claim is an intended use of the enzyme.

Nakamura et al. fails to disclose or suggest a protein expressed *in vitro*, comprising an isolated protein found intracellularly in *Eimeria* and is represented by the amino acid sequence shown in SEQ ID NO:2 and a vaccine for the protection of poultry against Coccidiosis comprising an effective amount of an isolated protein as described above.

Nakamura et al., at best, discloses a native intact *Eimeria*

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LDH protein. Nakamura et al. never mentions using these proteins as vaccines.

Again, Applicants respectfully asserts that Nakamura et al. fails to anticipate a "vaccine" claim.

Nakamura et al. fails to disclose each element of the present invention as set forth in the claims.

Applicants respectfully request withdrawal of the 35 U.S.C. §102(b).

Conclusion

All the stated grounds of the rejections have been properly traversed, accommodated or rendered moot. Applicants respectfully submit that the present application is in condition for allowance.

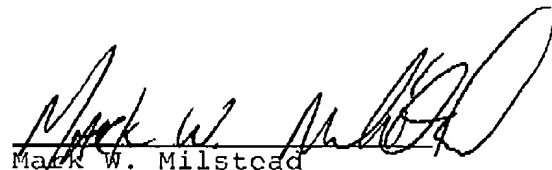
If the Examiner believes for any reason that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (302) 934-4395, in Millsboro, Delaware.

Pursuant to 37 C.F.R. §§1.17 and 1.136(a), Applicants respectfully petitions for a two month extension of time for filing a response in connection with the present application and the Commissioner is hereby authorized to charge the required fee of \$420 to Deposit Account No. 02-2334.

If necessary, the Commissioner is hereby authorized in this, concurrent, and further replies, to charge payment or credit any

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overpayment to Deposit Account No. 02-2334 for any additional
fees required under 37 C.F.R. §1.16 or under 37 C.F.R. §1.17;
particularly extension of time fees.

Respectfully submitted,



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